CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
75-051

BIOEQUIVALENCE

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

.etoclopramide Oral Solution	UDL Laboratories
5 mg/5 mL	Largo, FL
ANDA #75051	Submission Date:
Reviewer: Moo Park	December 30, 1996

REF PRODUCT	A. H. Robins' Reglan[R] Syrup, 5 mg/5 mL
BE STUDY DESIGN	n/a
STUDY SITE	n/a
STUDY SUMMARY	n/a
BIOASSAY VALIDATION	n/a
DISSOLUTION	n/a
WAIVER	1. Metoclopramide Oral Solution is an AA rated oral solution. 2. The test product contains metoclopramide in the same concentration as the reference product. The test product contains the same inactive ingredients qualitatively as the reference product except flavors and propylparaben. 3. Waiver is granted for UDL's Metoclopramide Oral Solution, 5 mg/5 mL strength.

INITIAL: Moo Park DATE: 6/6/97
REVIEWER: Moo Park, Ph.D.
BRANCH: III

INITIAL: Ramakant M. Mhatre DATE: 6/6/97
TEAM LEADER: Ramakant M. Mhatre, Ph.D.
BRANCH: III

The difference in amount of citric acid and glycerin should have no impact on BA/BE. Waiver appropriate under 320.22(b)(3)

INITIAL: [signature] DATE: 8/13/97
DIRECTOR: Nicholas Fleischer, Ph.D.
DIVISION OF BIOEQUIVALENCE

INITIAL: _____ DATE: _____
DIRECTOR
OFFICE OF GENERIC DRUGS

MAY 16 1997

Metoclopramide Oral Solution	UDL Laboratories
5 mg/5 mL	Largo, FL
ANDA #75051	Submission Date:
Reviewer: Moo Park	December 30, 1996
Filename: 75051w.d96	

Review of a Waiver Request

I. Objective

Review of UDL's waiver request for its Metoclopramide Oral Solution, 5 mg/5 mL strength. Reference product is A. H. Robins' Reglan^{R} Syrup, 5 mg/5 mL.

II. Comment

1. Metoclopramide Oral Solution is an AA rated oral solution.

2. The test product contains metoclopramide in the same concentration as the reference product. The test product contains the same inactive ingredients qualitatively as the reference product except flavors and propylparaben. These differences are not likely to affect absorption of the active drug ingredient. The test formulation is shown in Table 1.

Table 1. Test Formulation

Ingredient	Amount mg/5 mL
Metoclopramide Hydrochloride	(=5.0 as base)
Methylparaben	
Citric acid	
Sorbitol Solution	
Glycerin	
Artificial flavor	
FD&C Yellow	
Purified Water USP	

3. Waiver is granted for UDL's Metoclopramide Oral Solution, 5 mg/5 mL strength.

III. Deficiency

None.

IV. Recommendation

The Division of Bioequivalence agrees that the information submitted by UDL demonstrates that Metoclopramide Oral Solution, 5 mg/5 mL strength, falls under 21 CFR Section 320.22 (b) of the Bioavailability/ Bioequivalence Regulations. The waiver of *in vivo* bioequivalence study for UDL's Metoclopramide Oral Solution, 5 mg/5 mL strength, is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test Metoclopramide Oral Solution, 5 mg/5 mL strength to be bioequivalent to A. H. Robins' Reglan^{R} Syrup, 5 mg/5 mL.

The firm should be informed of the recommendation.

Moo Park

Moo Park, Ph.D.
Chemist, Review Branch III
Division of Bioequivalence

RD INITIALED RMHATRE
FT INITIALED RMHATRE Ramakant M. Mhatre 5/13/97
Ramakant M. Mhatre, Ph.D.
Team Leader, Review Branch III
Division of Bioequivalence

Concur: _____ Date: 5/16/97
for Nicholas Fleischer, Ph.D.
Director
Division of Bioequivalence

cc:

97)